IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JANE LAVOIE-FERN, SHERRY KONWALER, HARVEY HOROWITZ, and MARIE BRUEN, Plaintiffs, -vs- THE HERSHEY COMPANY, Defendant.	))))))))))))	Case No. 1:21-cv-01245-SHR (Judge Sylvia H. Rambo)

PLAINTIFFS' BRIEF IN OPPOSITION TO

DEFENDANT'S MOTION TO DISMISS

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Defendant's motion is patently wrong and must be denied. The NLEA does not apply to the claims in this case, and there is no conflict preemption.

ARGUMENT

Defendant makes two arguments. First, Defendant argues that Plaintiffs' state tort law claims are expressly preempted because they seek to impose obligations that are not identical to the requirements of 21 U.S.C. §343(i)(2). Second, Defendant argues that any allegation that defendant should not have used glycyrrhizin is conflict preempted. Defendant is wrong.

I. PLAINTIFFS' CLAIMS ARE NOT EXPRESSLY PREEMPTED BY THE NLEA

A. Preemption Within the Third Circuit

Defendant first argues that Plaintiffs' claims are expressly preempted because they seek to impose obligations that are not identical to the requirements of 21 U.S.C. §343(i)(2). Conspicuously, Defendant fails to cite any case law within this Circuit. This is for good reason.

In Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237 (3d Cir. 2008), the plaintiff appealed a decision of the district court, which granted the defendant tuna fish producer's motion to dismiss the consumer's action under the New Jersey Products Liability Act, on the grounds that the consumer's claims were preempted under the Supremacy Clause by the Food and Drug Administration's (FDA) regulatory approach. The consumer alleged that she was harmed as a result of her consumption of methylmercury and other harmful compounds contained in the tuna fish products. She sought recovery under the NJPLA, based on the producer's failure to warn of the risks incurred in consuming its products. The district court held that the claims were preempted by the FDA's regulatory approach to the risks posed by mercury compounds in tuna fish. The district court took judicial notice of an FDA consumer advisory, a "backgrounder," a section of the FDA's compliance policy guide, and a letter written by the Commissioner of the

FDA. In reversing and remanding the district court's decision, the court held that the FDA had promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, had adopted no rule precluding states from imposing a duty to warn, and had taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. The court held that none of the documents cited constituted a federal legal standard or binding regulatory action on the subject which could have given rise to a conflict.

The defendant cited three theories of preemption: "(1) that the FDA ha[d] adopted a "pervasive regulatory approach" -- embodied in the FDA's Advisory, backgrounder and internal enforcement guideline -- with which Fellner's state lawsuit actually conflict[ed]; (2) that the FDA ha[d] 'reject[ed] the use of warning labels' in favor of a more 'nuanced' approach -- that is, that the FDA ha[d] reached a decision that warnings should not be regulated, a decision which preempt[ed] the state from entertaining a claim based on a duty to warn theory; and (3) that the FDA would have rejected any warning as 'misbranding,' a determination which preempts Fellner's failure-to-warn claim." Id. at 242. The Third Circuit rejected each of these arguments.

First, the Court noted that the Defendant did not, and **could not** make any claims for express preemption under the FDCA, NLEA, or by federal regulation (presumably for the reasons discussed *infra* in I.B.). Id. at 243. Nor could there be any field preemption, because "courts rarely find field preemption, especially in areas traditionally regulated by the states, unless the structure of a regulatory program leaves little doubt that Congress intended federal law to be exclusive in a particular field." Id. at 243, n.3. The only possible preemption, the Court held, would be conflict preemption. Id. at 243.

The Court discussed that the Supreme Court historically has applied a presumption against the preemption of state laws unless there is a clear and manifest purpose of Congress to

do so. Id. at 248. The Court stated that recent Supreme Court jurisprudence suggested that the presumption remains applicable when preemption claims concern areas of the law "which the States have traditionally occupied," and that it was "hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product." Id. The Court stated that "[f]urthermore, state tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case. Federal regulatory programs frequently do not include a compensatory apparatus, and the Supreme Court has recognized that state tort law can also play an important information-gathering role not easily replicated by federal agencies. When a litigant asserts that a private right of action, as opposed to a state statute or regulation, is preempted, we are cognizant that preemption may leave individuals with rights but no private remedy, where traditionally there has been one. Although Congress certainly can afford, and in some instances has afforded, federal regulators exclusive jurisdiction over a particular subject matter, and federal regulations will preempt state laws that actually do conflict with them, we do not lightly infer such a result where state compensatory regimes have traditionally played an important role. Id. at 249.

With regard to the regulatory scheme argument, the Court held that the FDA had not promulgated any legal standards regarding warnings, and that even if the "regulatory scheme" was of a type that could preempt state law, the defendant had identified no conflict between the claims and regulatory scheme. Id. at 251-52. The Court found that the lawsuit did not conflict with the FDA's informal advice warning about the risks of mercury consumption in fish, and that rather, the concerns expressed therein were entirely consistent with, and arguably complementary to, a duty state law may impose on manufacturers to warn consumers of the risks

posed by excess consumption of tuna. Id. at 252. The Court likewise stated that the FDA's guideline for allowable levels of mercury, rather than conflict with the plaintiff's claim, instead were "entirely consistent with, and arguably complementary to, a state claim that Tri-Union wrongfully failed to warn consumers of the risks posed by those compounds." Id. The Court also rejected an argument that the FDA Commissioner had put out a letter that the FDA preferred not to use warnings for this issue, finding that "the letter itself does not establish a federal policy against warnings capable of preempting state law," and rejected a similar argument that the FDA had declined to mandate mercury warnings in response to a citizen's petition for them to do so, stating that "[t]he FDA merely explained that it would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited." Id. at 253, 253 n.10.

Next, the Court specifically rejected the argument that the FDA's decision not to regulate or mandate warnings preempted state law. Id. at 247. The Court stated that "[a]lthough the federal government certainly may promulgate a regulatory regime in which it decides that a particular issue is best left unregulated, as the Supreme Court has explained, 'to say that [such a regime] can be created is not to say it can be created subtly.' *Isla Petroleum*, 485 U.S. at 500. A mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn." Id. at 253. The Court concluded that "State law is not preempted whenever an agency has merely 'studied' or 'considered' an issue; state law is preempted when federal *law* conflicts with state law. As we have explained, the cases leave no doubt that a mere decision not to regulate -- in this case, a decision not to require a federal methylmercury warning -- alone will not preempt state law. *See supra* note 6 and accompanying text. As we have also explained, we find no federal standard, mandate or regulatory action on the

subject with which Fellner's claim conflicts nor any federal determination precluding state regulation of the issue." Id. at 254 (emphasis in original).

Finally, with regard to the argument that a warning would be preempted by the FDCA and NLEA, the Court stated that:

> Had the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning based on that data would be false or misleading under federal law -- **not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it** -- our recent decision in *Colacicco* would govern and a state failure-to-warn lawsuit would be preempted. However, Tri-Union's misbranding theory suffers from the same shortcomings as its prior theories: **it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it has identified actually conflict with Fellner's lawsuit.**
>
> The FDA has taken no misbranding action pertaining to the risk of mercury in tuna whatsoever. In the above-listed provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food -- "a suitable written notice or warning;" an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and affirmative regulation. However, the FDA has taken no action pursuant to this authority. Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after Fellner's injuries were allegedly suffered. We need not decide at what point a particular warning becomes established as false and misleading for preemption purposes. **Suffice it to say that the FDA must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law**; the informal views expressed in the Commissioner's letter will not preempt Fellner's lawsuit.
>
> Furthermore, as with its other preemption theories, TriUnion fails to identify an actual conflict between the FDA's concerns and Fellner's claims. We perceive no actual conflict between those concerns and Fellner's lawsuit. **Had Tri-Union wished to warn consumers of those risks, as Fellner alleges it should have, it is not apparent that Tri-Union would have been unable to do so in a manner that satisfied both the alleged state law duty and the FDA's concerns. For example, a warning certainly could have specified that the risks become material only with frequent tuna consumption,** and that moderate fish consumption offers positive health benefits. For these reasons, we find no actual conflict between the FDA's misbranding authority and Fellner's lawsuit.

Id. at 255-56 (emphasis added). The Court concluded its opinion that:

> This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's "regulatory scheme" for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter. Fellner's duty-to-warn claim does not conflict with an FDA determination deliberately to forego warnings because the FDA took no action to preclude state warnings -- at least, no binding action via ordinary regulatory procedures, and no action whatsoever until after Tri-Union allegedly wrongfully failed to warn. Finally, Fellner's lawsuit does not conflict with the FDCA's food misbranding provision or the FDA's actions thereunder because the FDA has not exercised its misbranding authority under the FDCA with respect to methylmercury warnings for fish.
>
> The FDA has only issued a consumer advisory regarding the risks posed by mercury in fish and established a guideline regarding mercury concentrations to guide its enforcement decisions. Neither of these agency acts constitutes a federal legal standard or binding regulatory action on the subject which could give rise to a conflict, and indeed neither expresses a policy or viewpoint or approach inherently inconsistent with Fellner's lawsuit. In the final analysis, this case involves an agency effort to preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred. We understand the precedent to require more of federal agencies to institute a policy expressly precluding state regulation than a mere informal letter, and neither the Commissioner's letter nor Tri-Union's brief identifies any federal law with which Fellner's lawsuit might conflict. Although the Supremacy Clause provides that state laws will give way when they actually conflict with federal law, on this record we find no federal law with which the alleged state duty to warn conflicts.

Id. at 256. As such, the Third Circuit reversed the district court's dismissal of the action.

Accordingly, the Third Circuit has explicitly rejected each of the arguments offered by Defendant. The FDA has promulgated no regulation concerning the risk posed by glycyrrhizin in candy or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing glycyrrhizin warnings as misbranding under federal law or as contrary to federal law. Instead, the FDA itself has itself put out warnings regarding the excessive consumption of black licorice (*see* **EXHIBIT 1**), and hence, just like in Fellner, this suit is entirely consistent with, and complementary to the FDA, and is not preempted.

Shortly after Fellner, the Supreme Court confirmed that if confronted with two plausible interpretations of a statute, the courts "have a duty to accept the reading that disfavors pre-emption." Holk v. Snapple Bev. Corp., 575 F.3d 329, 334 (3d Cir. 2009) (*citing* Wyeth v. Levine, 129 S. Ct. 1187, 1195, 173 L. Ed. 2d 51 (2009)). In Holk, the Third Circuit once again reversed a district court dismissal, finding that state-based claims related to "all natural" labels on Snapple bottles were not preempted by the FDCA, NLEA, implied preemption (which was prohibited under the NLEA), field preemption, or conflict preemption.

In Wyeth, the warnings on a drug's label were deemed sufficient by the FDA when it approved the manufacturer's new drug application in 1955 and when it later approved changes in the drug's labeling. The plaintiff alleged that the labeling was defective because when the risk of gangrene from IV-push injection of the drug became apparent, the manufacturer had a duty to provide a warning that adequately described that risk. The manufacturer failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted it to unilaterally strengthen its warning, and the mere fact that the FDA approved the drug's label did not establish that it would have prohibited such a change. There was powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. Accordingly, the Supreme Court held that the FDA's drug labeling judgments did not preempt state law product liability claims.

Hence, this is yet another reason why Defendant's arguments about glycyrrhizin's GRAS status from the late 70's and early 80's (addressed *infra*) must be rejected. There is no federal regulation that prohibits warnings when new information is discovered or learned. As the science revealed more and more danger from excess consumption of glycyrrhizin, there would be no reason why Defendant would not be able to warn consumers of such.

B. Defendant's NLEA Preemption Arguments

With the law of this Circuit now clear, Defendant's arguments can be addressed. As shown above, Defendant's arguments have all been specifically rejected by the Third Circuit. But even without the Third Circuit, Defendant's arguments are still wrong.

Defendant first argues that Plaintiffs' claims are preempted by the NLEA. Defendant, however, misstates the entire statutory scheme of the NLEA.

Under the NLEA, there are certain requirements that apply to certain foods and labeling. Under 21 U.S.C.S. § 343-1, where such requirements apply, no state is allowed to directly or indirectly establish that requirement if it is not identical to the federal requirement. In the absence of any such requirements, however, the NLEA is inapplicable and does not preempt.

Thus, for example, in Guerrero v. Target Corp., 889 F. Supp. 2d 1348 (S.D. Fla. 2012), the Court ruled as follows:

> The doctrine of federal preemption derives from the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, which invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) (*quoting Gibbons v. Ogden*, 22 U.S. 1, 6 L. Ed. 23 (1824)). Federal law preempts state law when there is "express preemption, field preemption, and implied conflict preemption." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) (*citing Hillsborough Cnty.*, 471 U.S. at 713). **"Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding."** *Holk*, 575 F.3d at 334. **In areas of traditional state regulation such as food and beverage labeling, "a presumption against preemption exists."** *Id*. (*citing Cipollone v. Ligett Grp., Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992)); *see also Smith v. CSX Transp., Inc.*, 381 Fed. Appx. 885, 886 (11th Cir. 2010). "[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77, 129 S. Ct. 538, 172 L. Ed. 2d 398 (2008) (internal quotation marks and citations omitted).
>
> Under the NLEA, "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for a food which is the subject of a

> standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) 13 of this title." 21 U.S.C. § 343-1(a)(1). The statute further provides that a state may not establish "any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section." 21 U.S.C. § 343-1(a)(3). Nonetheless, **the NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A 14 of the Federal Food, Drug, and Cosmetic Act." Nutrition Labeling and Education Act, Pub. L No. 101-535, § 6(c)(1)**.
>
> …
>
> The Court agrees with Plaintiff that the Florida Honey Standard is not expressly preempted by federal law. **When it enacted the NLEA, Congress was clear that it would not "preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act." Nutrition Labeling and Education Act, Pub. L No. 101-535, § 6(c)(1).** As Plaintiff points out, Congress has only expressly preempted standards of identity which conflict with established federal standards. *See* Response at 15. While Congress could have banned all state standards of identity, it did not do so. Other courts have noted that under the NLEA, "'the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements.'" *Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 372 (N.D. Cal. 2010) (*citing In re PepsiCo, Inc. Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008)). Here, the Florida Honey Standard does not conflict because there is no federal standard of identity for honey. The Court does not find any conflict between this conclusion and 21 U.S.C. § 343-1(a)(3) because, if a state has prescribed a standard of identity for a food product, the provisions of 21 U.S.C. § 343(i)(1) are not triggered. The Court thus declines to grant the Motion on the grounds that the Florida Honey Standard is expressly preempted by federal law.

Id. at 1360-63 (emphasis added).

Hence, as Section 403A (i.e. 21 U.S.C. § 343-1) does not expressly preempt placing a warning on a product against certain levels of consumption of a food product, the NLEA would not preempt a state's products liability claim. This is especially true, since "[i]n areas of traditional state regulation such as food and beverage labeling, 'a presumption against preemption exists.'" This is why Defendant speaks in broad strokes, and cannot point to any actual provision that would expressly preempt any labeling with respect to black licorice.

In fact, Defendant's own cited case states as such. Defendant relies upon Nemphos v.

Nestle Waters N. Am., Inc., 775 F.3d 616 (4th Cir. 2015), a Fourth Circuit case that Defendant contends supports Defendant's position. In fact, however, Nemphos disproves Defendant's position. In Nemphos the Court held that the plaintiff's claims were preempted only because the FDA had created a "standard of identity" for bottled water, and had also created specific regulations pertinent to fluoride level warning labels. Id. at 622-24. The plaintiff wanted a more detailed warning, even though the manufacturer had followed FDA regulations pertinent to fluoride level warning labels. Id. at 618. In fact, the FDA had previously considered and ultimately declined the plaintiff's desired regulations that were central to her complaint. Id. at 623. Because the claims effectively imposed greater obligations on the defendant manufacturers than that required by the FDA, the district court concluded the claims were preempted. In affirming this decision, the Fourth Circuit emphasized that the labeling requirements set forth in the complaint were "in addition" and "simply not identical to" the FDA's existing regulations. Id. at 625. The Court reasoned that the warning sought "would oblige Nestlé and Dannon to issue warnings about the risks of dental fluorosis for their products in the state of Maryland, even though the FDA resolved not to take that same step." Id. at 625-26.

The Court made sure to discuss that "[a] federal law may preempt state intervention in one aspect of a given food, for example, while allowing states to act on other aspects of the same food" (Id. at 619.), and that the NLEA only preempts those laws that it preempts expressly in its express provisions. Id. at 620. As explained by the Court, the food **must be** the subject of a federal standard of identity in order for the NLEA's preemption to apply. Id. at 621.

Additionally, the Court made sure to point out that:

> The NLEA does afford **a specific exception** to its preemption provisions -- for state-generated **"safety" warnings**. The preemption provisions in § 343-1 **do not "apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the**

> **food."** NLEA § 6(c)(2), 104 Stat. at 2364,, reprinted in 21 U.S.C. § 343-1, at 87. In the context of food additives, the FDA defines "safety" as entailing "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). Establishing "complete certainty" of "absolute harmlessness" is not required. Id. Although the NLEA's preemption provisions sweep broadly, **state-law duties may be insulated from the Act's preemptive reach if they involve warnings about food "safety."**

Id. (emphasis added), but that the plaintiff had not raised the issue. Id. at 625 n.5.

Accordingly, Defendant's argument is wrong for several reasons. First, there is no standard of identity here for the Twizzlers or Good and Plenty products at issue, so the NLEA does not apply.[1] In the cases cited by Defendant, the courts were dealing with items that had standards of identity and regulations as to how they could be labeled.[2] Second, there are no federal warning regulations here, so again, the NLEA would not apply. Third, this case deals with a safety warning, which is expressly excepted from the NLEA. And fourth, Plaintiffs are not seeking to mandate that Defendant have to do anything on its labels. Whether or not Defendant placed a warning (which contrary to Defendant's naked argument, would not have to vary by state) would be Defendant's choice. However, in the absence of Defendant voluntarily placing a warning on its labels, Defendant leaves itself open to suits for products liability and negligence. That is a conscious business choice to be made by Defendant; it is not a requirement by the

[1] Defendant cites to no case for the proposition that an ingredient's GRAS status creates a "standard of identity" for the product at issue. Every food product necessarily contains ingredients that would have GRAS status, and Defendant's argument would render meaningless the NLEA's applicability **only** to items with standards of identity. The issue in this case is not the labeling of the glycyrrhizin ingredient, but rather a warning relating to the consumption of the Twizzlers and Good & Plenty products. Defendant does not cite to a single document or citation that there is any standard of identity for these products.

[2] For example, Turek v. Gen. Mills, Inc., 754 F. Supp. 2d 956, 961 (N.D. Ill. 2010), dealt with using "insulin" and still labeling the product as containing "fiber," which had extensive substantive regulations governing the use of insulin and how it could be labeled, and labeling items as containing fiber and the accompanying health claims. Gubala v. CVS Pharmacy, Inc., 2015 U.S. Dist. LEXIS 77509, at *8-9 (N.D. Ill. June 16, 2015) likewise dealt with permissible labeling of whey protein, which also had extensive substantive regulations regarding permissible labeling of products as containing protein. And in Chi. Faucet Shoppe, Inc. v. Nestlé Waters N. Am. Inc., 24 F. Supp. 3d 750, 758-60 (N.D. Ill. 2014), the court dealt with labeling of "bottled water," which also was subject to extensive regulations, as discussed therein and in Nemphos. Hence, every single case cited by Defendant, including Nemphos as discussed above, dealt with items with standards of identity with extensive regulations as to permissible labeling of particular components, something distinctly absent in our case.

States to create any sort of requirement on Defendant.

II. THE NLEA EXPLICTLY EXCEPTS FOOD SAFETY WARNINGS

As discussed above, the NLEA expressly excepts from its preemptive reach safety warnings for food or any of its components. The plain language could not be clearer that the NLEA, or any preemption resulting therefrom, does not apply to this case.

Relying on two foreign district court decisions, however, In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig., 2009 U.S. Dist. LEXIS 104451, (W.D. Mo. Nov. 9, 2009) and Mills v. Giant of Md., LLC, 441 F.Supp.2d 104, 108–09 (D.D.C.2006), Defendant argues that because glycyrrhizin has GRAS status, the NLEA's clear food safety warning exception does not apply. Neither of these cases dealt with GRAS status.

Another district court has already dealt with the inapplicability of these two cases to a case like ours, as well as the faulty conclusion of In re BPA, and its words are better than any the undersigned would be able to come up with. In Sciortino v. PepsiCo, Inc., 108 F. Supp. 3d 780 (N.D. Cal. 2015), the Court explained:

> In sum, considering (1) the plain language of the government statutes, (2) the presumption against preemption of the states' historic police powers, *Medtronic*, 518 U.S. at 485, (3) the related requirement to accept, when plausible, the reading of an express preemption clause that disfavors preemption, *see Altria*, 555 U.S. at 77, (4) the evidence of Congress's intent not to regulate carcinogens or include state warning laws under the NLEA's express preemption provision, (5) the inclusion of a provision specifically saving state law claims based on warnings as to safety, and (6) Congress's consideration and lack of action as to specific legislation that would expressly preempt warning requirements such as those under Proposition 65, the Court concludes that it was not Congress's clear and manifest intent to include Proposition 65 warning claims within the scope of the NLEA's express preemption clause. Moreover, the Color Additive Amendments and the Delaney Clause under which the FDA issued its safety finding contain no express preemption clause.

Id. at 806-07. The Court masterfully dealt with the issue in some depth and detail, and the Court's opinion with the relevant highlighted portion is annexed hereto as **EXHIBIT 2**.

In short, the Court held that there was no express preemption by the NLEA, because requiring a warning was not covered under the NLEA "because the duties imposed by Proposition 65 are not 'of the type' of those imposed under the misbranding provisions subject to preemption; i.e., §§ 343(i) (common or usual name for food or ingredients) and 343(k) (labeling of any artificial coloring). Proposition 65 does not take issue with the use of the term 'caramel color' for the color additive at issue here. Instead, it addresses the safety of the compound that is a byproduct of the additive." Id. at 800. Moreover, even if the NLEA was somehow implicated, the plain language of the statute and legislative history made clear that food safety warnings were explicitly excepted and not preempted. Id. at 801-02. In re BPA's conclusion that a safety determination by the FDA precludes application of this food safety warning exception has to be rejected in light of the plain language, legislative history, and purpose of the NLEA. Id. at 802-05. Furthermore, the regulatory finding by the FDA that the additive was safe did not change this conclusion, because unlike the NLEA, the statute under which the safety determination had been made did not contain a preemption clause, and moreover the safety determination was not itself a regulation of "the labeling of food" so as to implicate the NLEA, but rather was a subsidiary finding predicate to a labeling determination. Id. at 806. Thus, the NLEA's food safety warning exception still clearly applied, and there was no preemption. Id. at 806-07.

Accordingly, Defendant's argument must be rejected. The GRAS status of glycyrrhizin does not remove the NLEA's food safety warning exception, and the NLEA is inapplicable.

III. THERE IS NO CONFLICT PREEMPTION

As a final point, Defendant argues based on some language in the complaint, that if Plaintiffs are suggesting that Defendant should have used a safer ingredient, that argument would be conflict preempted based on glycyrrhizin's GRAS status. For this contention, Defendant cites

to four cases, Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000); Backus v. Nestle USA, Inc., 167 F. Supp. 3d 1068 (N.D. Cal. 2016); Beasley v. Lucky Stores, Inc., 400 F. Supp. 3d 942 (N.D. Cal. 2019); and Hawkins v. Kellogg Co., 224 F. Supp. 3d 1002 (S.D. Cal. 2016).

However, Defendant's argument is wrong for two important reasons. First, Plaintiffs have never said that Defendant should have to use a different ingredient. What Plaintiffs' complaint states (in the very paragraphs referenced by Defendant) is that Defendant's continued use of glycyrrhizin instead of a safer alternative, despite knowing its safety concerns, while simultaneously refusing to provide a warning to consumers, demonstrated Defendant's conscious indifference and utter disregard for the effect of its product upon the health, safety and rights of others, and thereby Defendant acted wantonly and recklessly. Defendants have never suggested that Plaintiff should be mandated to use a different ingredient, or that its use of glycyrrhizin was somehow not allowed. Accordingly, Defendant's argument never even gets off the ground.

Relatedly and more importantly, the cases cited to by Defendant all dealt with claims by plaintiffs under California's unlawful business practices law and related statutes, seeking to hold the defendant liable for the use of a produce that was unlawful, and/or to make it immediately unlawful to sell any product with the ingredient. *See, e.g.*, Beasley, 400 F. Supp. 3d at 949; Hawkins, 224 F. Supp. 3d at 1013; Backus, 167 F. Supp. 3d at 1070. All three of these cases revolved around products containing partially hydrogenated oils ("PHOs), which the FDA had removed from GRAS status, prompting the FDA to issue a regulation that they must be removed from all foods by the end of three years, and Congress passing a law saying that no food with a PHO would be considered unsafe or adulterated until such deadline. The three decisions therefore held that any claims seeking to declare foods with PHO's unlawful or unfair prior to the deadline were conflict preempted by the FDA and Congress' pronouncements thereto. And

finally, Geier, which was not a food case, did not involve any sort of substitute, but rather sought to hold the defendant liable for not having an air bag in the car. The Court held that the Federal Motor Vehicle Safety Standard (FMVSS) 208 specifically allowed manufacturers to choose among different passive restraint mechanisms, such as airbags, automatic belts, or other passive restraint technologies, and that the Department of Transportation had specifically rejected a proposed FMVSS 208 "all airbag" standard, and moreover also deliberately sought a gradual phase-in of passive restraints. 529 U.S. at 878-79. As such, the Court held that the claim was conflict preempted, because the state tort law being used under would be an obstacle to the accomplishment of FMVSS 208's objective. Id. at 886.

Here, Plaintiffs do not seek to hold Defendant liable under any sort of unlawful or unfair business practice statute, nor a declaration that the sale of any product containing glycyrrhizin is unlawful or an unfair business practice. Nor have there been any sort of regulations from the FDA or Congress related to the use of glycyrrhizin, such that Defendant using an alternative ingredient would be an obstacle to the accomplishment of a regulatory or congressional objective. As such, Defendant's case law is simply inapplicable to this case, and its argument must be rejected.

CONCLUSION

For the foregoing reasons, Defendant's motion must be summarily denied.

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